UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ALERE INC., ALERE SWITZERLAND GmbH, and SPD SWISS PRECISION DIAGNOSTICS GmbH,

Plaintiffs,

v.

CHURCH & DWIGHT COMPANY, INC.,

Defendant.

Civil Action No. 10-10027 (DPW)

DEFENDANT'S OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

On January 8, 2010, Inverness Medical Innovations, Inc. (now "Alere Inc."), Inverness Medical Switzerland GmbH (now "Alere Switzerland GmbH"), and SPD Swiss Precision Diagnostics GmbH ("SPD") (hereinafter collectively referred to as "Plaintiffs") filed a Complaint against defendant Church & Dwight Co., Inc. for infringement of U.S. Patent No. 7,317,532 (the "'532 Patent"). In its July 20, 2010 Amended Complaint ("Am. Comp."), Plaintiffs alleged infringement of the '532 Patent and two additional patents – U.S. Patent No. 7,239,394 (the "'394 Patent") and U.S. Patent No. 7,315,378 (the "'378 Patent").[1]

In their Preliminary Infringement Contentions filed pursuant to Local Rule 16.6(A)(1) of this Court, as amended, Plaintiffs have alleged that defendant's FIRST RESPONSE® GOLD digital pregnancy test infringes claims 1-5, 8, 10-15, 18, 21-24, 26-27 of the '394 Patent, claims 18 and 20 of the '378 Patent, and claims 19, 21-22, 24-27 of the '532 Patent. Defendant submits this brief in support of its proposed claim constructions in relation to the asserted claims.

II. SUMMARY OF THE PATENTS-IN-SUIT

The patents-in-suit all claim priority to the same provisional patent application[2] subsequently incorporated by reference into each of the three applications which issued as the patents-in-suit. The provisional application recites that it is directed to an assay device including a reader of an assay test strip which detects "the presence and/or amount of analyte present in a fluid sample wherein under certain circumstances, a negative or positive result may be displayed earlier than usual." (Ex. 4 at 3.) One of the commercial applications for the disclosed technology is the detection of a hormone associated with pregnancy – human chorionic gonadotropin (hCG). *Id.* at

[1] Copies of the patents-in-suit are attached as Exhibits 1, 2, and 3.

[2] Application No. 60/508001, filed 10/02/2003, entitled "Assay Devices and Methods." (*See* Ex. 4.)

6. The provisional application acknowledged that home pregnancy test kits were already widely known (*Id.*), and, each of the patents-in-suit is directed to a purported improvement upon such assay devices.

A. The '394 Patent

The '394 Patent (Ex. 1) is closely related to the "early result" feature discussed in the provisional application and, unsurprisingly, is entitled "Early Determination Of Assay Results." Specifically, the Summary of the '394 patent states: "The reader can, under certain circumstances, determine a positive or negative result (*i.e.*, the presence and/or amount of an analyte in a test sample) before an assay has completed." ('394, 2:25-28.)[3] After describing the type of pregnancy tests that were on the market at the time, the patentees described what they perceived as a shortcoming in those devices – "It is necessary to wait for a particular period of time to elapse after the test has commenced in order to read the result." ('394**,** 1:43-45.) They divulge that others had dealt with this issue by 1) providing instructions for the user to wait for a prescribed period of time after the sample has been applied in order to view the result; 2) generating a perceptible signal to the user indicating that a sufficient period of time had elapsed in order to read the test; or 3) including a timing mechanism such that the result is only displayed after a preset period. ('394, 1:58 - 2:4.) According to the patentees, these solutions still "require a preset time to have elapsed before the result is read or displayed" ('394, 2:10-11), whereas "there is a natural desire on the part of the user to have the result as soon as possible." ('394, 2:17-19.)

The patentees then proposed an alternative assay device where in certain circumstances the reader may be "able to display the results as soon as conveniently possible rather than necessarily wait for a preset time to elapse." ('394, 3:51-53.) The alleged invention employs an optical

[3] Throughout this brief, defendant will refer to excerpts from the patents-in-suit in the following format – patent number, column:line (or range of lines). Thus, '394, 2:25-28 refers to the '394 patent, at column 2, lines 25 through 28.

detection system, such as a photodetector, to generate a digital signal whose value reflects the amount, or rate of accumulation, of an analyte in a detection zone of the assay device. ('394, 4:1-14; 8:43-54.) The reader is programmed to make an initial determination of the signal value at some preset time ('394, 5:55-57, 8:66 - 9:1), and if the conditions for an early result are not present, to repeat those measurements at regular intervals. ('394, 6:19-37.) To determine if an early result can be displayed, the value of the signal read by the optical system is compared against two "thresholds" to determine the reader's course of action. According to the patent, an "upper threshold" is set such that "signal levels below this value are regarded as negative … and levels above are regarded as positive." ('394, 3:27-29.) One of the early results comes from a comparison against this upper threshold:

> In the case of a high analyte concentration, the reading will cross the upper threshold limit at an earlier time and therefore an earlier than usual result may be displayed. ('394, 3:39-41; *see also* 9:8-10.)

In addition, the patentee defines a "lower threshold" against which a predictive result can be made before the assay's usual completion time.

> If after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the upper threshold even if the reaction were allowed to proceed to completion, and an early negative result is then displayed. This would represent the case of a fluid sample having a very low analyte concentration. ('394, 3:30-36; *see also* 9:11-15.)

In short, for very low analyte concentrations it is determined that if the signal reading is still low (*i.e.*, below the lower threshold) at some predetermined time, it can be predicted that the result will never cross the upper threshold (*i.e.*, a positive result) even if the test runs its full duration. ('394, 9:11-15 – "Referring to plot 3, at t(1) the initial reading is below the value of L, so the reader can promptly declare a negative result, since it can be predicted that the value will never exceed the upper threshold before the predetermined endpoint of the assay t_e.") (emphasis added). It is important to note that if the test were to run to its endpoint t_e ('394, 6:1; Fig. 3), the result,

positive or negative, would be determined by the upper threshold only. ('394, 3:27-29, 6:1-4; *see also* 9:21-23 – "For plot 2, the final reading at t_e is still below the value of U, so the assay result would be negative.") (emphasis added.) The lower threshold is used only as an early predictor of a negative result.

For intermediate cases (*i.e.*, where the signal has crossed the lower threshold in that certain period of time, but does not exceed the upper threshold), the reader will take further readings ('394, 5:63-67, 6:19-21, 9:1-8, 9:16-19; Fig. 3) until the reading crosses the upper threshold. ('394, 3:43-47, 6:19-27.) If the signal reading does not pass the upper threshold before the predetermined end-point of the test (t_e), a negative result is declared. ('394, 3:47-50, 6:23-27, 6:32-36, 9:21-23.)

B. The '532 Patent

In the '532 Patent (Ex. 2), filed concurrently with the '394 Patent, the patentees noted that the flow rate of fluid in a test carrier was not uniform from test to test. ('532, 2:11-27.) This non-uniformity of flow is said to lead to inaccurate results. Specifically, the patent discloses:

> In some cases the carrier has a tendency to flood, i.e. the fluid front moves along the carrier at a faster rate than normal. Conversely, in some cases, it has been noted that the fluid front moves along the carrier at a much slower rate than normal, namely the carrier is blocked to some extent. It has been found that these different types of fluid flow-rate behavior can give rise to inaccurate results. ('532, 2:28-33.)

To solve this problem, the patentees stated it would be desirable to "be able to determine the extent and/or rate at which the liquid sample moved along the porous carrier and to reject those readings where the flow rate was determined to fall outside of predetermined limits. ('532, 2:42-46.) The patent therefore discloses the addition of a "control feature" to the device for calculating a flow rate of the fluid flowing between spaced apart zones on the carrier. ('532, 2:41-42, 5:16-17.)

> Conveniently the flow rate is calculated between two zones on the liquid transport carrier, such that the presence of the liquid sample at, or passage thereof through, a first, upstream zone is detected, and likewise the present [sic] of the liquid sample at, or passage through, a second, downstream zone is detected. If the distance between the two zones is fixed and/or known, the relative or absolute flow rate of

> the liquid sample can be readily calculated by measuring the amount of time which elapses between detection of the liquid sample at the first and second zones. ('532, 4:32-41.)

If the calculated flow rate is outside of predetermined limits, the assay can be declared invalid. ('532, 5:14-16; *see also* 8:58-61, 9:5-10.)

C. The '378 Patent

The '378 Patent (Ex. 3) is directed to an optical arrangement for an assay reading device. Specifically, it discloses various multi-detector/multi-zone arrangements for the optical components of the reader which fall into one of two categories – a "shared" photodetector arrangement, in which one detector "is used to detect light emanating from two distinct zones of the test strip" ('378, 2:34-41), or a "commonly read" zone arrangement, in which two or more detectors read a common zone. ('378, 2:42-49.)

These optical arrangements address small misalignments. Where a detector is located between two zones, the signal from one zone would be less intense if misalignment moved it away from the detector and moved the other zone closer to the detector. ('378, 3:24-37.)

Solely by reference to the '394 Patent, the '378 Patent suggests the detection of "early results" in a reader with the disclosed optics.

> An assay result reader according to the present disclosure may also include a system for declaring the result of an assay before completion of the assay, if a [sic] analyte measurement signal is above an upper threshold or below a lower threshold. ('378, 9:62-67.)

III. LEGAL PRINCIPLES REGARDING CLAIM CONSTRUCTION

A. General Principles of Claim Construction

Claim interpretation is a question of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-90 (1996). In interpreting a claim, the Court looks to three primary sources: the claims, the specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17

(Fed. Cir. 2005)(*en banc*). *Phillips* reaffirmed that the specification rather than a dictionary is the "single best guide" to the meaning of the disputed claim language. *Id.* at 1320-21 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Still, it is proper to give the language of the claims the ordinary and customary meaning that would be attributed to it by one of ordinary skill in the art at the time of the invention, so long as it aligns with the description of the invention in the patent:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors *actually* invented and intended to envelop with the claim. *The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.*

Phillips, 415 F.3d at 1316 (emphasis added).

B. Courts Do Not Redraft Claims To Sustain Their Validity

Courts "may not redraft claims, whether to make them operable or to sustain their validity." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004). "Even a nonsensical result does not require the court to redraft the claims of the …patent." *Id.* Thus, a claim that violates one of the requirements for patentability as the patentee wrote it must be invalidated, not redrafted. *Id.* ("We construe the claim as written, not as the patentees wish they had written it.") A claim that fails to particularly point out what the inventor regarded as his invention with a clarity sufficient to demarcate the boundaries of the claimed property right is invalid under the second paragraph of 35 U.S.C. § 112 for indefiniteness. *Id.*

There is also a written description requirement in 35 U.S.C. § 112, which is separate from the enablement requirement of that provision.[4] *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d

[4] 35 U.S.C. § 112 (first paragraph) reads: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated

1336, 1344 (Fed. Cir. 2010). "The adequacy of the written description (*i.e.*, the disclosure) is measured from the face of the application." *New Railhead Mfg., LLC v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002). "The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, [the] application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). "It is not sufficient for purposes of the written description requirement of § 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood*, 107 F.3d at 1572. "What is claimed by the patent application must be the same as what is disclosed in the specification: otherwise the patent should not issue." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002).

C. The Role of the Prosecution History

The prosecution history plays an important role in claim interpretation, by demonstrating how the inventor understood his invention and how the PTO understood the patent. *Phillips*, 415 F.3d at 1317. Courts naturally study the Examiner's Reasons For Allowance. Where an Examiner states that he is allowing a claim because the prior art fails to show specified features believed to be inventive, and the inventor does not dispute that statement, the Examiner's statement may be used, as appropriate, to construe the allowed claim. *Koepnick Med. & Educ. Research Found. v. Alcon Labs.*, 162 Fed. Appx. 967, 971-72 (Fed. Cir. 2005) (examiner's recitation that prior art does not teach "cutting two disks from the eye" supports construction of "excising" as "cutting out."); *Cytyc*

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by the inventor of carrying out his invention.

Corp. v. Tripath Imaging, Inc., No. 03-11142-DPW, 2005 WL 3177877 at *10 (D. Mass. Nov. 28, 2005) (holding examiner's reasons for allowance relevant to claim construction).

D. The Use of Extrinsic Evidence

Extrinsic evidence, such as inventor testimony, dictionary definitions, and expert testimony, may be considered by the Court in construing claim language, but it is subordinate to intrinsic evidence as a guide to claim construction. *Phillips*, 415 F.3d at 1318-19. Dictionary definitions and other objective reference materials available at the time that the patent was issued provide evidence of a claim's ordinary meaning. *Phillips*, 415 F.3d at 1314, 1321-23.

E. Means Plus Function Claims

With respect to the means-plus-function phrases at issue, the Court must first identify the claimed function and then determine what structure in the specification corresponds to the claimed function. *Cardiac Pacemakers, Inc. et al. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). The specification must clearly associate the structure with performance of the function. *Id.* Where the specification discloses only a single structure corresponding to the claimed function, the element is no broader than that structure and its equivalents. *Cortland Line Co. v. Orvis Co.,* 203 F.3d 1351, 1357 (Fed. Cir. 2000) ("[b]ecause the specification describes only one structure corresponding to the connecting function, this court limits" the construction to that structure and equivalents thereof.)

IV. THE PROPER CONSTRUCTION OF THE CLAIMS

A. Undisputed Terms

Pursuant to the Court's Scheduling Order the parties exchanged their respective claim constructions and conferred as to whether they could reach agreement as to the meaning of any of the terms. The parties have agreed as to the construction of the following terms:[5]

Claim Term	Agreed Construction
"terminate the assay" (Claim 1 of the '394 Patent)	end the analysis before the predetermined end-point of the assay.
"an output signal" (Claims 1 and 26 of the '394 Patent)	an audio or visual signal provided to the user before the predetermined end-point of the assay.
"a first output signal" (Claim 18 of the '378 Patent)	a first audio or visual signal provided to the user before the predetermined end-point of the assay.
"a second output signal" (Claim 18 of the '378 Patent)	a second audio or visual signal provided to the user before the predetermined end-point of the assay.
"the assay has been completed" (Claims 22, 24 of the '394 Patent)	the predetermined end-point of the assay.
"a processor configured to … determine a result indicative of a time required for a liquid received by the sample receiving zone to flow from the first zone along the flow path to the second zone" (Claims 24, 26 of the '532 Patent)	a processor that calculates a result that represents the time it takes the liquid to flow the distance from the first zone to the second zone.

The parties have also agreed upon the meaning of the following means plus function element of Claim 22 of the '394 Patent:

[5] The parties also agreed that "porous test strip" in claims 24 and 26 of the '532 Patent does not need to be construed.

"means for declaring the result of the assay if the determined rate or amount of signal accumulation exceeds the upper threshold value or is below the lower threshold value or at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value before the assay has been completed"	Function: declaring the result of the assay if the determined rate or amount of signal accumulation exceeds the upper threshold value or is below the lower threshold value or at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value before the predetermined end point of the assay. Corresponding Structure: a sound or light source such as LED, a display such as alphanumeric or an LCD

B. Construction of the Disputed Terms

1. The '394 Patent

a) "a signal representing the amount of an analyte or the rate of accumulation of an analyte" (Claims 1, 23, 26, 27) [6]

Claim Limitation	Defendant's Construction
a signal representing the amount of an analyte or the rate of accumulation of an analyte	A signal which is a value indicative of the amount of analyte in a detection zone or the rate of its accumulation in the detection zone.

As explained in the specification of the '394 Patent, the assay conducted by the claimed device generally operates by accumulating a detectable substance in a detection zone on a test strip within the device. ('394, 3:4-17.) The accumulation of the detectable substance is caused by the presence (or absence) of an analyte of interest (*i.e.*, the analyte being tested). ('394, 3: 18-23.) For example, a reagent immobilized in the test zone may bind to labeled analyte as it flows through the test zone. ('394, 4:1-4.)

The reader will then optically detect accumulation of the label (*e.g.*, a colored particle attached as a label to an analyte such as hcG) in the detection zone and generate a digital signal

[6] At least for claims 1 and 26, Plaintiffs expressed a desire to construe this term in the context of the full limitation, that is, "a computation circuit, responsive to a signal representing the amount of an analyte or the rate of accumulation of an analyte." In that case, defendant asserts the construction should be: "A circuit that processes [*insert defendant's construction above*]."

proportional to the amount of label accumulated by tracking changes in the amount of reflected light. ('394, 4:5-9.) The specification provides as a specific example:

> The amount of signal is a measure of the light absorbed, or the decrease in light reflected, from the test zone of a lateral flow test stick as might be determined using the assay result reader described in the preceding example. In the presence of the analyte of interest, a coloured particulate labeled binding reagent accumulates in the test zone. The coloured particulate label absorbs some of the light incident upon the test zone, and this reduces the amount of light reflected therefrom which is available for detection by a suitably positioned photodetector. The higher the concentration of analyte, the more rapid the rate of accumulation of label in the test zone and the stronger the "signal." ('394, 8:43-54.)

In other words, a colored particle attached to the analyte absorbs light to reduce the amount of reflected light converted into an electrical signal by the photodetector. The "signal" is then related to the amount of analyte as follows: "The amount of light reaching the photodetector depends upon the amount of coloured particulate label present and therefore the amount of analyte." ('394, 4:64-67.) Accordingly, the signal is a value reflecting the amount of analyte in the detection zone.

The specification further discloses that if measurements of the amount of signal are taken at two or more time points, then the rate of signal accumulation can be calculated. ('394, 6:37-42.) Thus, the signal can be a value reflecting the amount of analyte, or the rate of its accumulation, in a detection zone. Permissible variations of the signal are described at '394, 9:24-41. However, as will be discussed *infra* in section IV.B.2, the file wrapper of a family member of the '394 Patent establishes that the "signal" itself is not the difference between two values from two different zones.

b) "upper threshold value" (Claims 22, 24)

Claim Limitation	Defendant's Construction
upper threshold value	A value below which the determined value of signal accumulation is regarded as a negative result and above which values are regarded as a positive result.

The specification provides an explicit definition for "*upper threshold value*" -- "the upper threshold value is set such that signal levels below this value are regarded as negative (i.e. the analyte is not present) and levels above are regarded as positive." ('394, 3:27-29.) *Phillips*, 415 F.3d at 1316 ("our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.") The upper threshold is, in fact, the value that determines the ultimate result of the assay test. At any time during the assay, if the upper threshold is exceeded, a positive result is declared. ('394, 2:34-37, 2:44-46, 3:27-29, 3:38-42, 3:46-47, 6:23-27, 6:32-36, 9:8-10.) If the upper threshold is not reached by the predetermined endpoint of the test, t_e, a negative result is declared. ('394, 3:47-50, 6:23-27, 6:32-36, 9:21-23.)

One difference in the parties' constructions is whether or not a threshold can vary during the course of an assay and whether the means plus function limitations discussed *infra* in section (i) can possibly embrace a variable threshold in a single use assay. The patent is clear that the only time a threshold should vary is from one assay to the next in a series of related assay tests, not within an individual assay. In this regard, the '394 Patent states:

> … the values of the at least upper and lower threshold limits may be adjusted during the course of the assay reading. This may occur on the basis of the readings obtained earlier in the course of the assay. ('394, 9:46-49.)

However, it immediately continues:

> It is preferable however that these values remain constant during the course of an individual assay. ('394, 9:49-51, emphasis added.)

No disclosure is made of any actual way of using variable threshold values in a one-time test and varying the threshold in the one-time embodiment disclosed would render it inoperable. The use of variable thresholds applies where multiple tests are required to track the amount of analyte over time, such as over a series of days. ('394, 10:46-49 – "some embodiments may

employ a series of test strips in order to track the amount of an analyte over time, and to adjust the threshold values from strip to strip in the series order to provide precise results.") Such would be the case, for example, in an ovulation test where a surge in the LH hormone is monitored over the course of days and a peak detected indicating the day on which a woman is beginning to ovulate. ('394, 10:51-54.) However, pregnancy tests are performed in a single assay and thus do not require varying thresholds. The patent makes the distinction between these two types of assay clear:

> The above-described examples refer to assay result reading devices that work as one-time tests; i.e., a single test strip is assayed for a single test result. The threshold values typically remain fixed from test to test for reliability and reproducibility." ('394, 10:41-45.)

Nowhere does the patent disclose, or even suggest, how a one-time assay type test, such as pregnancy tests, could use a varying threshold. Indeed, the opposite is the case. In describing the one-time tests, the patentees always refer to a fixed threshold. Fig. 3 of the '394 Patent illustrates this and the description conforms: "Also shown on the graph are two horizontal lines which indicate the upper threshold ("U") and lower threshold ("L") values respectively." ('394, 8:63-65.) As shown in the figure, the lines for "L" and "U" demonstrate constant thresholds throughout the duration of the assay (*e.g.*, a horizontal line). In fact, the early prediction mode of the invention relies on the upper threshold being constant. The specification expressly says "an early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached equilibrium." ('394, 9:41-45.) If the upper threshold were permitted to change during the test, this prediction could never be made.

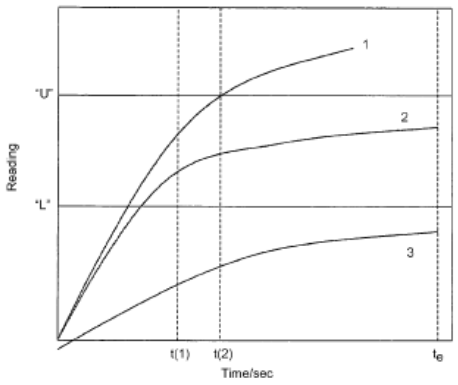

Fig. 3

c) "lower threshold value" (Claims 22, 24)

Claim Limitation	Defendant's Construction
lower threshold value	A value which, if not reached after a certain period of time, indicates that the signal value will never reach the upper threshold value.

The patentee explained the meaning of "*lower threshold value*" as follows:

> If after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the upper threshold even if the reaction were allowed to proceed to completion, and an early negative result is then displayed. This would represent the case of a fluid sample having a very low analyte concentration. ('394, 3:30-36.)

As discussed above, the lower threshold is not the dividing line between actual positive and negative results, it is only used to provide a prediction that the upper threshold will never be reached. As explained with reference to Fig. 3 of the patent, if a reading is below the value of L (the lower threshold) at a certain predetermined time after commencement of the assay (*see, e.g.*, plot 3 at t(1) in Fig. 3), "it can be predicted that the value will never exceed the upper threshold before the predetermined end-point of the assay t_e." ('394, 9:13-15 – emphasis added.) In all other circumstances, declaration of a result is predicated on the comparison to the upper threshold. ('394, 2:34-37, 3:38-42, 3:46-47, 6:23-27, 6:32-36, 9:8-10.)

d) "first threshold" (Claims 1, 26)
"first threshold value" (Claims 23, 27)

Claim Limitation	Defendant's Construction
first threshold first threshold value	A value above which measured values of the signal are regarded as a "first result" and below which they are regarded as a "second result."

The "*first threshold*" or "*first threshold value*" is closely related to the "upper threshold value" discussed above, with a slight modification. Consequently, the discussion in section (b) applies. While the positive result was inherent in the definition of "upper threshold" (if the signal value exceeds it), based on its use in the claims, the same is not true of "first threshold."

Claims 1 and 26 declare first and second "results," respectively, if the signal exceeds the first threshold or is less than the second threshold. Dependent claim 2 adds that the "first result" is positive and the "second result" is negative. Accordingly, under the doctrine of claim differentiation, claim 1 is not so limited, and may cover the reverse situation, where a signal which exceeds the "first threshold" produces a "first result" which is a negative; and similarly, a signal which is less than the "second threshold" produces a "second result" which is a positive result. (*See* '394, 3:18-23.) Defendant's proposed construction accounts for this possibility.

e) "second threshold" (Claims 1, 26)
"second threshold value" (Claims 23, 27)

Claim Limitation	Defendant's Construction
second threshold second threshold value	A value which, if not reached after a certain period of time, indicates that the signal value will never reach the first threshold.

Defendant's proposed construction for "second" threshold differs from "lower" threshold only in substituting "first" for "upper." Thus, section (c) and the reasoning of section (d) apply.

f) "the signal" (Claims 1, 23, 26, 27)
"the determined rate or amount …" (Claims 22, 24)

Claim Limitation	Defendant's Construction
the signal the determined rate or amount of signal accumulation	Each recitation in a claim refers to the same signal value or the same value of the determined rate or amount of signal accumulation.

Each of claims 1, 23, 26, and 27 compare "*the signal*" to each of a first threshold and second threshold. Each of claims 22 and 24 compare "*the determined rate or amount of signal accumulation*" with each of an upper threshold and a lower threshold.

It is an undisputed tenet of claim construction that use of the definite article "the" indicates that the same thing is being referred to each time. *See, e.g.*, *Furminator, Inc., v. Ontel Prods. Corp.*, 429 F. Supp. 2d 1153, 1171 (E.D. Mo. 2006) ("As described earlier, indefinite and definite

articles are used in patent claim drafting in order to define precisely when the second or third or tenth reference to a particular thing … is the same thing that is being referred to in the first use of that noun. This is a basic rule of patent claim drafting over which there is no debate or issue."), *aff'd*, 214 Fed. Appx. 982 (Fed. Cir. 2007); *Microprocessor Enhancement Corp. v. Texas Instruments, Inc.*, No. SA CV 05-323 AHS, 2007 WL 840362, at *4 (C.D. Cal. Feb. 8, 2007), *rev'd on other grounds by* 520 F.3d 1367 (Fed. Cir. 2008) ("Where subsequent uses of a claim term within a claim make reference to the first usage as an antecedent (through the use of introductory definite articles such as 'said' or 'the'), the claim term must be interpreted consistently across all such uses.").

Thus, by the plain language of the claims, "the signal" compared to the first threshold in each claim must be the same "signal" that is compared to the second threshold in each claim. Similarly, "the rate or amount of signal accumulation" compared to the upper threshold in each of claims 22 and 24 must be the same "rate or amount of signal accumulation" compared to the lower threshold. The Federal Circuit has confirmed that in such circumstances it must be the same "value" of the signal used in both instances and not values at different points in time. *Yamaha Corp. v. ESS Tech., Inc.*, No. 95-1362, 82 F.3d 435, 1996 WL 146499, at *3 (Fed. Cir. March 29, 1996) ("If Yamaha meant for 'the output' in the final clause to refer to a different value in time from that in the first step, it could have explicitly so stated."); *see also*, *Ampex Corp. v. Eastman Kodak Co.*, 460 F. Supp. 2d 541, 549 (D. Del. 2006) (holding multiple uses of "the data" to require the same luminance and chrominance values for each pixel of an image).

The specification also supports this construction. The patent discloses that the reader is programmed to make a "first determination of the rate or amount of signal accumulation" at a

predetermined time. ('394, 5:55-57.) That measured value is then tested in the recited comparison steps of each claim to test for the existence of early results.

> "If however the determined rate or amount of signal accumulation is above the lower threshold but below the upper threshold, the assay must be continued. The signal in this instance may be said to be an intermediate signal. … Desirably the assay result reader will be programmed so as to repeat the test measurement if an intermediate signal is obtained." ('394, 5:63 – 6:20.)

In short, the signal value read at the first measurement interval is compared to both thresholds, and only if determined to be an "intermediate" signal is a subsequent measurement ever taken and any further comparisons performed.

In light of the clear intrinsic evidence, as well as the law, the same "signal" value (or value of the rate or amount of signal accumulation), and not values taken at different points in time, must be used in each of the comparisons recited in the claims.

g) "amount of signal accumulation" (Claims 22, 24)

Claim Limitation	Defendant's Construction
amount of signal accumulation	A value indicative of the amount of signal representing the amount of analyte in a detection zone.

For the reason the term of paragraph (a) has been construed, this term should be construed consistently. See paragraph (a) above for a discussion of the meaning of this term.[7]

h) "equilibrium" (Claims 23, 24, 26, 27)

Claim Limitation	Defendant's Construction
Equilibrium	That point in time, before the predetermined end point of the assay, after which the rate of change of the signal will not lead to a change in the assay result.

[7] Defendant believes construction of this term resolves the relevant issues for the means plus function elements in which it is contained. However, defendant reserves its right to respond to additional issues raised by Plaintiffs in their construction of the means plus function clause containing this element.

"Equilibrium" appears only once in the specification:

> [A]n early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached **equilibrium**. ('394, 9:41-45.)

From surrounding claim language, it is clear that equilibrium can not be the time at which the assay has been completed (*i.e.*, the predetermined end-point – *see Undisputed Terms,* section IV.(A)). Both "equilibrium" and the term "the assay has been completed" appear in claim 24 and thus these terms are presumed to have different meanings. *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) ("we must presume that the use of ... different terms in the claims connotes different meanings.").

Equilibrium is the point in time before the predetermined end-point after which the signal is not changing in a way which would lead to a change in the assay result. According to the patent, in prior art tests predetermined end points were set to provide an accurate reading, *i.e.*, when the test had developed to the point where the result would not change. (*See, e.g.*, '394, 1:42-49, 1:53-56, 2:14-16.) Similarly, the ordinary meaning of "equilibrium" is a "condition in which no change occurs in the state of a system as long as its surroundings are unaltered." *See, e.g.,* Ex. 5: The McGraw-Hill Dictionary of Scientific and Technical Terms (6th ed. 2003). Merriam Webster's Collegiate Dictionary (10th ed. 1997) offers that "equilibrium" is a state of "balance." (*See* Ex. 6.)

Recalling that the patent recited that the purpose of the invention was to provide a result as "soon as conveniently possible" without waiting for a "preset time to elapse" ('394, 3:51-53), it is apparent that equilibrium is some time before the predetermined end-point t_e, the time when the signal is already at equilibrium and not changing in a way which would lead to a change in the assay result.

i) the means-plus-function threshold comparisons in Claim 22

Claim Limitation	Defendant's Construction
means for comparing the determined rate or amount of signal accumulation with an upper threshold value;	Function: comparing the determined rate or amount of signal accumulation with an upper threshold value.
means for comparing the determined rate or amount of signal accumulation with a lower threshold value;	Function: comparing the determined rate or amount of signal accumulation with a lower threshold value. Structure: A CPU or microcontroller programmed with the algorithm disclosed in the patent for achieving the claimed function or an equivalent structure.

In Claim 22, since the elements reciting the comparisons of "*the determined rate or amount of signal accumulation"* with the upper and lower threshold values are recited in means-plus-function format (*see* '394, 14:45-48), it is necessary, first, to identify the function of each limitation and then identify the structure disclosed in the specification clearly identified as performing the claimed function. *Cardiac Pacemakers*, 296 F.3d at 1113. In relation to function, the "*amount of signal accumulation*" is discussed in section (g) above, and as discussed in section (f) above, the same signal measurement must be used in each comparison due to the use of the definite article "*the*." Threshold values have been discussed in sections (b) and (c).

Here, the functions are performed by a central processing unit or microcontroller. ('394, 5:4-6, 5:11-14.) However, a patentee cannot simply recite a general purpose computer. *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008) ("Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to 'the corresponding structure, material, or acts' that perform the function, as required by section 112 paragraph 6.") "In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the

disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999); *see also In re Katz Interactive Call Processing Pat. Litig.*, -- F.3d --, 2011 WL 607381, at *5-6 (Fed. Cir. Feb. 18, 2011). Simply put, "the corresponding structure for a § 112 ¶ 6 claim for a computer-implemented function is the algorithm disclosed in the specification." *Harris Corp. v. Ericsson Inc.,* 417 F.3d 1241, 1249 (Fed. Cir. 2005). Thus, we review the patent for its disclosure of the algorithm, or programming, that performs the recited functions.

At the bottom of column 5, the specification discloses the algorithm used in the CPU to perform the claimed comparison functions. The reader is "programmed" to take an initial reading at a predetermined time. ('394, 5:55-57.) The program checks to see if that initial reading "exceeds the upper threshold or is below the lower threshold," and if so, "the assay can be safely terminated and the results (positive, negative, or a semi-quantitative result) indicated to the user." ('394, 5:58-63.) In the disclosed algorithm, the same reading - the initial reading - is compared to both the upper and lower thresholds.

Only if the initial reading is between the two thresholds (*i.e.*, "an intermediate signal") is the assay continued. ('394, 5:63-65.) The patent further confirms that the reader is programmed to repeat the test measurements "if an intermediate signal is obtained" ('394, 6:19-21) and preferably at regular intervals thereafter "until the signal exceeds the upper threshold or until t_e." ('394, 6:22-27.) Notably, there is no indication that subsequent measurements are compared against the lower threshold; but rather only to see if it "exceeds the upper threshold." ('394, 6:26-27.) This follows from the fact that the algorithm proceeded to this point only because it had earlier been determined this was an intermediate signal already exceeding the lower threshold.

Figures 2 and 3 reflect the structure and results of the algorithm, respectively, and are further described in the patent at 8:56 – 9:23 in relation to Example 2. Example 3 provides additional description of the application of the algorithm to a pregnancy test ('394, 9:60 – 10:36.)

Notably, there is no algorithm describing, directly or indirectly, the use of a variable threshold for a one-time test. ('394, 10:38-45.) Only in the succeeding description of Example 4, related to multiple tests and the portion of the algorithm describing the operation of an assay employing a "series of test strips" to detect an LH surge over several days is there a discussion of how to vary a threshold:

> Thus, the algorithm chooses the threshold on the basis of the previous day's measurement, but it could also be an average of the previous days measurements. ('394, 10:64-66, *see also* 10:51-63.)

Thus, the disclosed algorithm (*i.e.*, structure) performs a comparison against both thresholds only once, on the initial reading, and both comparisons are performed using the same initial signal measurement. Moreover, the disclosed algorithm only permits for adjustment of the thresholds between repeated tests (*see,* '394, 10:46-67.) No algorithm is disclosed for using a variable threshold in a one-time test and to do so would render the claimed test inoperative as discussed *supra* at 12-13. Therefore, the algorithm that corresponds to a one-time test employs a fixed threshold and follows the sequence of steps recited above at pp. 19-20 and equivalents.

j) "at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value" (Claims 22 and 24)

Claim Limitation	Defendant's Construction
at such time when it is determined that the rate or amount of signal accumulation will not exceed or is not likely to exceed the lower threshold value	Claims 22 and 24 cannot be construed as written and be valid.

The specification discloses declaring an early assay result in at least three instances. First, there is an early positive result:

> a result can be promptly displayed if the rate or amount of signal accumulation crosses the upper threshold limit." ('394, 3:38-40, emphasis added; *see also,* 5:58-63, 9:8-10.)

Second, there is an early predicted negative result:

> if after a certain period of time, the rate or amount of signal accumulation has not reached the lower threshold limit, it is considered that the signal will never reach the upper threshold even if the reaction were allowed to proceed to completion, and an early negative result is then displayed." ('394, 3:30-34, emphasis added; *see also*, 5:58-63.)

In describing an example of the early negative scenario the patent states:

> Referring to plot 3, at t(1) the initial reading is below the value of L, so the reader can promptly declare a negative result, since it can be predicted that the value will never exceed the upper threshold before the predetermined end-point of the assay t_e. ('394, 9:11-15, emphasis added.)

Third, the patent discloses that in some cases an early negative result can still be predicted for what was originally considered an "intermediate signal" (*i.e.*, a signal between the lower and upper thresholds):

> Furthermore, an early result may be promptly declared after the reading has exceeded the lower threshold but the reader determines that the result will not exceed the upper threshold value before the reading has reached equilibrium. ('394, 9:41-45, all emphasis added.)

In every situation disclosed in the patent, the result is conditioned upon actually reaching the upper threshold or a determination that the signal will never reach the upper threshold within a certain time. There is no description of what the disclosed reader will do at such time as it may determine that a signal "will not exceed or is not likely to exceed the lower threshold value" as recited in Claims 22 and 24. As such, these claims are indefinite and violate the description requirements of § 112 and must be held invalid. *See Festo,* 535 U.S. at 736; *Chef Am.,* 358 F.3d at 1374; *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002) (holding claim indefinite that mistakenly recited "perpendicular" rather than "parallel"). It is not clear that the patentee had any such embodiment in mind at the time of his application and an interpretation of

what he might have envisioned is pure speculation. *See Lockwood, supra*. In such circumstances, Courts do not redraft claims as the patentees wish they had been written. *See Chef Am., supra* (refusing to redraft claim reciting that dough be heated to a certain temperature when specification disclosed heating oven to that temperature); *Allen Eng'g Corp*., *supra* ("It is of no moment that the contradiction is obvious: semantic indefiniteness of claims 'is not rendered unobjectionable merely because it could have been corrected.'")

2. The '378 Patent

Plaintiffs have asserted only independent claim 18 and dependent claim 20 from the '378 Patent. Defendant believes the following terms of those claims need to be construed:[8]

- *an input signal representing the amount of an analyte or the rate of accumulation of an analyte*;
- *first threshold*;
- *the input signal*; and
- *second threshold*.

The only disclosure in the '378 Patent of the generation of outputs based on a comparison of a signal against two thresholds comes from its incorporation by reference of the '394 Patent. ('378, 9:60-67, 10:15-18.) Thus, except as indicated below, defendant contends these terms should have the same meanings as their counterparts in the '394 Patent as discussed above.

Notably though, the prosecution history of the '378 Patent sheds additional light on the proper construction of the element "*an input signal representing the amount of an analyte or the rate of accumulation of an analyte*."

[8] In connection with claims 1, 22-24, 26, and 27 of the '394 Patent as well as claim 18 of the '378 Patent, Plaintiffs assert a need to construe "result of an assay" and variants of it. Defendant believes no construction is required beyond the plain meaning, reserving the right to respond to Plaintiff's assertions.

Original claim 14 in the application for the '378 Patent recited essentially the same limitation that appears in issued claim 18:

> *a computation circuit, responsive to an input signal representing the amount of an analyte or the rate of accumulation of an analyte*… ('378 File History, Ex. 7 at 21.)

The Examiner stated he was allowing claim 14 because:

> The prior art of record taken alone or in combination fails to disclose a method or device whereby the amount of analyte or the rate of accumulation of analyte is compared to upper and lower thresholds in order to determine the validity of the assay as recited with the elements and steps of claim 14. Bolduan compares two measured values and determines if the difference between them is below a threshold in order to determine the validity of assay, but does not compare either value to both an upper and lower threshold. Eisenmann compares two values and determines if a relationship between the two values exceeds a threshold. Markart also compares two values and relates them to a threshold, but does not determine if either value is within a specified range. ('378 File History, Ex. 7 at 68, all emphasis added.)

In short, in allowing claim 14 the Examiner found that multiple prior art references recited the use of a signal that measured the difference between two values from two different zones in its subsequent comparison steps.[9] The purportedly novel feature was the comparison of a value taken from one zone to both an upper and lower threshold. The patentees did not object to the Examiner's reasons for allowance and thus it is appropriate to consider his remarks in construing the claims. *See Koepnick; Cytyc, supra.*

Thereafter, the patentee added application claim 22 with the same claim term recited in claim 14 (Ex. 7 at 163.) Claim 22 issued as Claim 18 in the '378 Patent. (*Id.* at 325.) Consequently, the "signal" limitation in issued Claim 18 must be construed consistently.

[9] For example, Markart generates a signal ΔR (the difference between optical signals in regions 26 and 28, *see* Fig. 5), which is then compared to "a pre-given threshold value." (Markart, Ex. 8, 4:35-50; Figs. 1, 3, 4, 5.) Bolduan also discloses the use of a "difference" signal compared to a threshold to flag a result: "If the difference between the reflectance values obtained from the areas B_1 and B_2 exceed the predetermined threshold value then an appropriate message is displayed on the display (Z)." (Bolduan, Ex. 9, 8:66 – 9:2; Fig. 1.) Eisenmann similarly flags a result if "the difference between the reflectivity value R1 and the reflectivity R2 at a time T does not reach a pre-given threshold value…" (Eisenmann, Ex. 10, 4:25-27; Figs. 4 and 5.)

This construction is equally valid for the same term recited in claims 1, 23, 26, and 27 of the '394 Patent. *Abtox, Inc. v. Exitron Corp.*, 131 F.3d 1009, 1010 (Fed. Cir. 1997) ("Although these claims have since issued in separate patents, it would be improper to construe this term differently in one patent than another, given their common ancestry."); *see also Kimberly-Clark Corp. v. Tyco Int'l, Inc.*, 4 Fed. Appx. 946, 950 (Fed. Cir. 2001). Indeed, the portion of the file history of the '378 Patent quoted above is actually incorporated into the file history of the '394 Patent. *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004) (holding then existing prosecution history of one application part of another when it was cited in a double patenting rejection.)[10]

Accordingly, in addition to the construction proposed in section (1.a) above, the "signal" term in claims 1, 23, 26, and 27 of the '394 Patent and claim18 of the '378 Patent cannot be construed to encompass a signal which is a difference between two measured values taken from two different zones.

3. The '532 Patent

a) "a sample application zone" (Claim 19)
"first portion of the liquid transport carrier" (Claim 21)
"sample receiving zone" (Claims 24 and 26)

Claim Limitation	Defendant's Construction
a sample application zone first portion of the liquid transport carrier sample receiving zone	A region on the liquid transport carrier where a user applies a liquid.

[10] A provisional double patenting rejection was made against claim 1 of the '394 Patent by citing claim 14 of the application for the '378 Patent. ('394 File History, Ex. 11 at 53.) By that time, the reasons for allowing claim 14 had been stated in the '378 prosecution history and became a part of the '394 prosecution history. *Goldenberg, supra.*

These terms simply refer to the region of the carrier or test strip where the sample being tested is collected from the user of the device. The plain language of the claims supports this construction. For example, claim 19 recites "a liquid applied to a *sample application zone.*" ('532, 16:56-57.) Claim 21 recites "*a first portion of the liquid transport carrier* being wet with a liquid" ('532, 17:18-19), and claims 24 and 26 read a "liquid received by the *sample receiving zone*." ('532, 18:10, 18:42-43.)

The specification also supports this. It states: "Liquid sample suspected of containing analyte is applied to the porous carrier …" ('532, 1:32-34.) The following two passages also support this:

> …a test strip is inserted into the reader, and a liquid sample is then added to a sample receiving portion of the test strip. Alternatively a liquid sample may be applied to the test strip first, and the strip then inserted into the reader." ('532, 8:22-26.)
>
> To conduct an assay, a sample receiving portion of the test stick is contacted with the liquid sample. In this case of a urine sample, the sample receiving portion may be held in a urine stream, or a urine sample collected in a receptacle and the sample receiving portion briefly (for about 5-20 seconds) immersed in the sample. ('532, 10:59-64.)

Nothing more is implied and there is no inherent geometric relation between the application zone and the first and second zones also recited in the claims. The patent expressly states: "the first and second zones may be anywhere on the liquid transport carrier…" ('532, 4:42-43.)[11]

b) "selectively illuminate each of the first and second spaced-apart zones" (Claim 19)

Claim Limitation	Defendant's Construction
selectively illuminate each of the first and second spaced-apart zones	To independently choose which of the first and second zones to illuminate.

[11] This passage alone refutes the construction Plaintiffs intend to offer on various claim elements relating to the spaced-apart zones, a limitation on which Defendant reserves further comment until its response brief.

Claim 19 recites detecting light separately from each of two separated zones. The specification teaches, in the context of a shared detector system (*e.g.*, one detector reads multiple zones), how the respective zones are independently illuminated so that the detector can isolate the signal emanating from each zone. The specification suggests temporal selection as one option:

> The microcontroller 18 switches on the LED's 10 one at a time, so that only one of the three zones is illuminated at any given time – in this way the signals generated by light reflected from the respective zones can be discriminated on a temporal basis. ('532, 10:25-29, emphasis added.)

As an alternative to temporal selection, the patent further explains how a system using three LEDs can structurally isolate each LED so as to selectively illuminate only its intended target:

> Each LED is optically isolated by light-impermeable baffles 40, which ensure that the various LEDS are capable of illuminating only its respective zone of the test strip. ('532, 13:66 – 14:1, emphasis added.)

In either case, light from a particular light source is ensured to illuminate only one desired zone so that the signals can be independently read. Thus, configuring the light system for "selectively illuminating" makes it possible to choose which zone is to be read.

c) "to determine [determining] a flow rate of liquid " (Claims 19 and 21)

Claim Limitation	Defendant's Construction
to determine [determining] a flow rate of liquid	To calculate the speed (*i.e.*, distance per time unit) of the liquid's flow.

As discussed earlier, the '532 Patent discloses that it is necessary to calculate the flow rate of the liquid in the test device to monitor for "blocked" or "flooded" samples so as to avoid inaccurate results. (*See section II.B*). The patent demonstrates that the patentee used the term "flow rate" to mean speed of flow (*i.e.*, distance / time). This calculated speed is then compared against "predetermined limits" ('532, 2:46; *see also* 3:9-11, 3:26-27, 8:58-61, 9:7-8) to reject erroneous results.

Thus, "flow rate" is not expressed as a time, but rather as distance per time unit. The specification of the '532 Patent itself indicates that the calculation of the flow rate requires time and distance as inputs – the time that elapses between liquid detection in each of two zones, and the distance between those zones:

> Conveniently the flow rate is calculated between two zones on the liquid transport carrier, such that the presence of the liquid sample at, or passage thereof through, a first, upstream zone is detected, and likewise the present [sic] of the liquid sample at, or passage through, a second, downstream zone is detected. If the distance between the two zones is fixed and/or known, the relative or absolute flow rate of the liquid sample can be readily calculated by measuring the amount of time which elapses between detection of the liquid sample at the first and second zones. ('532, 4:32-41, emphasis added.)

Thus, the calculation of flow rate involves elapsed time but is not that alone. After describing various arrangements for the photodetectors to sample and detect the presence of liquid in each of the zones, the patent further states:

> From analysis of the voltage-time profiles for the respective zones and with knowledge of the distance between the zones, the rate of fluid flow may be determined. ('532, 8:46-48, emphasis added.)

Thus, the patentee defined that determining a flow rate involves dividing the distance between the zones by the measured time elapsed for the fluid to be detected in each zone. In addition, for at least two reasons "determining a flow rate" cannot be construed as simply monitoring whether fluid reaches a particular zone within a time cutoff. First, in numerous places the specification distinguishes between calculating a flow rate and determining the extent of progress of fluid (*i.e.*, whether fluid has reached a particular zone). *See, e.g.*, 2:40-44, 2:58-62, 5:25-27, 5:34-37, 5:38-39, 5:40-44, 6:10-16, 8:58-61, 9:4-8. Specifically, the patent states: "It is preferred to calculate the rate of progress of the liquid sample (rather than the extent thereof) along the liquid transport carrier." ('532, 4:29-31, emphasis added.)

Second, during prosecution of the '532 Patent, the Examiner made statements that make clear that monitoring the presence or absence of fluid as a function of time or determining when wetting occurs is not the same as determining a flow rate. Specifically, Claim 1 of the application for the '532 Patent recited claim language essentially similar to the term under discussion – "a computation circuit … to calculate a flow rate for a fluid flowing along the carrier." ('532 File History, Ex. 12 at 25.)[12] In a June 17, 2005 Office Action, the Examiner indicated that claims 1 and 14 had allowable subject matter because "the prior art does not disclose an optical device or method for monitoring the flow rate of a fluid on a liquid transport carrier." (*Id.* at 63, emphasis added.) The Examiner expressly noted however, that the prior art of record did disclose monitoring the presence of fluid as a function of time:

> Pan et al (US 2002/0192833 A1) teaches monitoring the presence or absence of fluid on a test strip as a function of time, but does not determine the flow rate of the fluid. Markart (US 5,889,525) discloses measuring changes in light transmittance or reflectance in two zones of a test strip at repeated time intervals, but does not use this information to calculate a flow rate. Tajnafoi (US 6,448,067) monitors the intensity of reflected light from a test strip over a period of time, and determines when wetting occurs, but does not use this information to calculate a flow rate. (*Id.* at 63.)[13]

Clearly, the Examiner understood that "calculating a flow rate" as claimed included something more than simply monitoring the presence of fluid on a test strip as a function of time as taught by the prior art. To distinguish the prior art, there needed to be an actual determination of the flow rate.

[12] Original claim 14 contained language parallel to issued method claim 21: "calculating a flow rate of the liquid sample along the carrier." ('532 File History, Ex. 12 at 27.)

[13] Markart, Pan, and Tajnaföi are attached as Exs. 8, 13, and 14, respectively.

Claims 19 and 21 were subsequently added to the application using the language recited in the heading of this section which is essentially similar to the language in allowed claims 1 and 14. Those claims were also allowed,[14] the Examiner stating:

> As to claim 19, the prior art of record, taken alone or in combination, fails to disclose or render obvious a device comprising a processor configured to determine a flow rate of liquid along a liquid transport carrier based at least in part on signals indicative of light detected from first and second zones, in combination with the rest of the limitations of claim 19. (*Id.* at 173.)[15]

Once again, as the patentees never objected to the Examiner's comments or reasons for allowance, such comments are appropriate to consult for purposes of claim construction. *See Koepnick; Cytyc, supra.*

In view of the above, the "determination of a flow rate" should be construed as the actual calculation of the speed (*i.e.*, distance divided by unit of time) of the liquid's flow and not just a measurement of the presence of fluid at a particular zone within some generalized period of time.

V. CONCLUSION

For all the reasons stated, Church & Dwight requests that each of its proposed constructions be adopted.

[14] Claim 21 was subsequently rejected and amended on other grounds before issuing.

[15] The Examiner made an equivalent statement about method claim 21, though apparently inadvertently repeated "claim 19" in his comment. (*See* '532 File History, Ex. 12 at 173.)

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The undersigned hereby certifies that this document was filed through the ECF system on March 25, 2011 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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